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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/313,942	05/19/99	STAHL	REG-203-A

HM22/0227  
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EXAMINER

O HARA, E

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 02/27/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/313,942

Applicant

Stahl et al.

Examiner

Eileen B. O'Hara

Group Art Unit

1646

☒ Responsive to communication(s) filed on Dec 7, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-25 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-25 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

1. Claims 1-25 are pending in the instant application.

#### ***Information Disclosure Statement***

2. The reference on the Information Disclosure Statement has been considered.

#### ***Drawings***

3. The Examiner acknowledges that Applicant will resubmit Figures 4 and 9 upon the receipt of a Notice of Allowance , at the time of the submission of formal drawings.

#### ***Withdrawn Rejections***

4. The rejection of claims for double patenting is withdrawn in view of Applicant's amendment.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 1-25 remain rejected under 35 U.S.C. § 103(a) as being obvious over Stahl et al., PN 5,844,099, for reasons cited in the previous Office Action, Paper No. 9, at pages 4-5.

Applicants request reconsideration and withdrawal of the rejection, and assert that having the fusion proteins do not necessarily require possession of the nucleic acids, and while clearly nucleic acids of the present application can encode fusion proteins, the inventions are patentably distinct. Applicants further argue that it would be exceedingly difficult for one, from the fusion proteins disclosed in the '009 patent, to determine the specific nucleic acids of the present invention.

Applicants arguments have been considered but are not found persuasive. The nucleic acids encoding specific amino acids is old and well known, and one of skill in the art would immediately grasp the structure of the nucleic acids required to make the fusion proteins disclosed in the '009 patent. The skilled artisan would find it obvious to make the fusion proteins using nucleic acids, and would be motivated to do so, because it is widely acknowledged in the art that this is the most effective way to make fusion proteins.

Applicants further argue that the nucleic acids of the present invention are not taught or suggested by the '099 patent. The nucleic acids of the present invention encode fusion proteins which contain on a single molecule the three components specified in the claims which are:

(a) a cytokine binding portion of the extracellular domain of the specificity determining component of a cytokine receptor,

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- (b) a cytokine binding portion of the extracellular domain of the signal transducing component of a cytokine receptor, and
- (c) a multimerizing component.

Applicants assert that the '099 patent discloses a molecule wherein an immunoglobulin derived domain forms a complex between the extracellular domain of the specificity determining component and the extracellular domain of the signal transducing component, and that in the present invention, the multimerizing component forms a complex between polypeptides that contain all three components on the same molecule. Applicants further assert that at the time of the invention in the '099 patent, one of skill in the art would not have contemplated placing all three of the above components on a single molecule in view of lack of knowledge at the time about the exact mechanism underlying the way the components bind to a cytokine and the potentially steric hindrance envisioned, and that the '099 patent does not teach or suggest the present invention as claimed.

Applicants arguments have been considered but are not found persuasive. At column 9, lines 6-20, the '099 patent teaches that heterodimers can be prepared by expression as chimeric molecules utilizing flexible linker loops, in which a DNA construct expresses two domains fused together in tandem by a flexible loop, which may be artificial or from a naturally occurring protein (e.g. the hinge region of hIgG). These molecule may be engineered in which the order of the domains is switched, and/or in which the length and composition of the loop is varied, to allow for selection of molecules with desired characteristics. The DNA constructs so described

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are single chain molecules, so therefore the '099 patent does teach and suggest the present invention as claimed.

It should be noted that the double patenting rejection has been withdrawn because the claims are not obvious over the claims of the '099 patent, but the claims are obvious over the disclosure of the patent. Therefore, the rejection under 35 U.S.C. 103 is maintained.

It is believed that all pertinent arguments have been answered.

### ***Conclusion***

6. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D

Patent Examiner

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in dark ink and is positioned to the left of a typed nameplate.

LORRAINE SPECTOR  
PRIMARY EXAMINER